REMARKS

The title has been changed to more accurately reflect the claimed invention.

Claims 1-18 have been canceled and new claims 19-34 submitted. Newly submitted claims 19-29 and 31-34 substantially track previous Claims 1-10.

Claim 19 specifies the claimed nucleic acid molecule encode a protein comprising an at least 20 amino acid region identical in sequence to a 20 amino acid region from SEQ ID NO:5. Support for such nucleic acid molecules can be found in the specification, for example, on page 23, lines 17-23, through page 24, lines 1-3.

Claims 20 and 30 specify the claimed nucleic acid molecule encode a protein at least about 95% identical to SEQ ID NO:5 or SEQ ID NO:10. Support for such nucleic acid molecules can be found in the specification, for example, on page 24, lines 7-10.

Claim 24 specifies the claimed nucleic acid molecule comprise a nucleic acid sequence comprising an at least 45 contiguous nucleotide region identical to a contiguous nucleotide region from SEQ ID NO:4. Support for such nucleic acid molecules can be found in the specification, for example, on page 22, lines 21-23, through page 23, lines 1-6.

Claim 25 and 32 specify the claimed nucleic acid molecule comprise a nucleic acid sequence at least 95% identical to SEQ ID NO:4, SEQ ID NO:7 or SEQ ID NO:10. Support for such nucleic acid molecules can be found in the specification, for example on page 24, lines 19-23, through page 25, lines 1-5.

Claim 29 is drawn to an isolated nucleic acid molecule comprising a means for encoding a canine IL-5 protein operatively connected to a means for promoting expression from the canine IL-5 protein encoding means. Support for such a nucleic acid molecule can be found in the specification, for example, on page26, lines 14-23, through page 28, lines 1-19, and page 48,lines 16-23, through page 49, lines 1-15.

Accordingly, Applicants submit new mater has been entered in the Application.

Claim Objections

The Examiner has objected to Claims 4 and 18 stating the designation "nCaIL-5_{1658}" is unclear. Applicants note Claims 4 and 18 have been canceled. The newly submitted claims do not use internal designations and instead refer to nucleic acids using SEQ ID NO's.

Rejections Under 35 U.S.C.§112, first paragraph-written description

The Examiner has rejected Claims 1, 3, 5-11, 13-14 and 17 under 35 U.S.C§112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner states that while invention as claimed encompasses any and all allelic variants, homologs and natural and non-natural variants of SEQ ID NO:'s 18 and 19 and of nucleic acid molecules encoding the amino acid sequence of SEQ ID NO's 5 or 10, the specification fails to disclose any variants having the claimed activity. The Examiner contends that at best, the specification discloses the sequences of SEQ ID NO:18 and 19, and the protein encoded by these sequences. According to the Examiner, the specification fails to define the minimum structure or consensus core sequence that defines the claimed genus, and instead, defines the claimed variants only by a statement of function. The Examiner therefore concludes that one of skill in the art would conclude Applicants were not in possession of the claimed genus.

Applicants note Claims 1-18 have been canceled rendering the Examiner's rejections moot. However, Claims 19, 20 , 24, 25, 30 and 32, while not specifically referring to variants, refer to small nucleic acid molecules or nucleic acid molecules having specific percent identities to which some of the Examiner's comments apply. In anticipation of this, Applicant's respectfully disagree with the Examiner's conclusion that one of skill in the art would conclude that Applicants were in possession of nothing more than SEQ ID NO's 18, 19 or the proteins encoded by these sequences.

The core of the Examiner's argument is that the specification fails to identify the minimal structure or consensus core structure that defines the claimed genus and that Applicants have defined the claimed genus only by a statement of function. With respect to the newly submitted claims, Applicants respectfully disagree. Applicants have clearly disclosed the full length sequence of the canine IL-5 protein and the DNA encoding this protein. Claims 19 and 24 refer, respectively, to nucleic acid molecules encoding 20 amino acid fragments of the full length protein or to isolated nucleic acid molecules having at least 45 nucleotides identical to the disclosed sequence. Applicants contend that since the specification discloses the full length gene and protein, all nucleic acid molecules encoding 20 amino acid stretches of canine IL-5 and all nucleic acid molecules comprising at least 45 nucleotides identical to the disclosed nucleotide

sequence are inherently disclosed. It would be a simple matter for one of skilled in the art to look at the disclosed sequence and synthesize, or produce, a nucleic acid molecule falling within the scope of the instant claims. With respect to nucleic acid molecule 95% identical, Applicants contend the same logic applies. Applicants have disclosed the core sequence of canine IL-5. One of skill in the at would easily be able to look at the core sequence and make changes in the sequence so that the altered sequence is no more that 5% divergent from the disclosed sequence. Given that there are only 19 amino acids that can be substituted at each position, there are a finite number of molecules that will be 95% identical. While Applicants have not literally disclosed each and every sequence, Applicants submit that a requirement to do so would make the Application unnecessarily cumbersome; the wording "95% identical" can be viewed as a type of shorthand, providing a mathematical description of the claimed genus. As described above, one skilled in the art would could apply this mathematical description to the core sequence and easily arrive at each and every member of the claimed genus. With regard to those molecules having 95% identity and having the stated activity, Applicants assert it is unnecessary to teach which molecules have the stated activity. Applicants have taught assays with which to test molecules. One skilled in the art would be able to follow the instant teaching and test any particular molecule for the claimed activity. While it is true that a certain percentage of molecules 95% identical to the stated sequence will not have the specified activity, these will not fall within the scope of the claims and therefore will not be of concern. Therefore, in view of the above, Applicants submit the newly submitted claims meet the written description requirements.

The Examiner has rejected Claims 11-16 under 35 U.S.C.§112, first paragraph, as failing to meet the written description requirement. Applicants note claims 11-16 have been canceled. The newly submitted claims do not refer to therapeutic uses of the instant nucleic acid molecules or to methods of regulating an immune response using the instant nucleic acid molecules. Therefore, with respect to the newly submitted claims, this rejection is moot.

Rejections Under 35 U.S.C. §112, first paragraph- enablement

The Examiner has rejected Claims 1-10 and 17-18 under 35 U.S.C. §112, as failing to comply with the enablement requirement. Specifically the Examiner states that while the specification enables one skilled in the art to make or use the nucleic acid sequence of SEQ ID

NO's 18 or 19 which encode the amino acid sequences of SEQ ID NO:5 and 10, it does not enable one skilled in the art to make all variants of SEQ ID NO's 18 and 19 having IL-5 activity. The Examiner contends the invention, as claimed, is unpredictable since the specification fails to teach the conserved amino acid sequences required for IL-5 like activity and the claimed variation will encompass conserved motifs germane to IL-5 activity. The Examiner contends that since the number of scenarios increases geometrically with the increase in percent non-identity, one would need to engage in extensive making and testing in order to obtain the variants that meet the requirement of the claims. The Examiner concludes such testing would require one skilled in the art to engage in undue experimentation.

Applicants note Claims 1-18 have been canceled making the previous rejection moot. However, Claims 20, 25, 30 and 32 refer to nucleic acid molecule having 95% identity with specified SEQ ID NO's and having a stated activity; therefore, some of the Examiner's comments would apply to these new claims. In anticipation of this, Applicants respectfully disagree with the Examiner's conclusion that the specification fails to enable one skilled in the art to make nucleic acid molecules having, or encoding a protein having, 95% identity to the stated SEQ ID NO's.

The core of the Examiner's argument is that the specification fails to enable one skilled in the art to be able make all sequences having, or encoding a protein having, 95% identity with a specified SEQ ID NO and having the specified activity. Applicants respectfully disagree. The specification clearly discloses the claimed nucleic acid molecules; see for example page 24, lines 7-23, through page 25, lines 1-5. Based on the teaching provided in the specification, and the abilities of one skilled in the art, a practitioner would have no trouble making all nucleic acid molecules 95% identical to the stated SEQ ID NO's or encoding a protein having a sequence 95% identical to a stated SEQ ID. Similarly, one skilled in the art could easily look at the disclosed sequences and produce a nucleic acid molecule having at least 45 contiguous nucleotides identical in sequence with the disclosed SEQ ID NO's or a protein having at least 20 amino acids identical in sequence with the disclosed SEQ ID NO's. While it may be possible that not all of these sequences will have the claimed activity, the specification clearly teaches assays with which to test the molecules; see for example page 23, lines 17-23 through page 24, lines 1-3 and page 49, lines 16-23, through page 52, lines 1-22. Using such teaching, one skilled the art would quickly and easily be able to determine which of the sequences, having the stated

sequence variation, also have the stated activity. The Examiner appears to steadfastly believe that Applicants are required to teach exactly which nucleotide/amino acid changes are allowable while still retaining the stated activity. Applicants believe that not only would a requirement for such disclosure be unfairly restrictive, it is unnecessary and contrary to established case law. Applicants contend that it is enough that the specification discloses the core sequence and describes, mathematically, all the envisioned variations from this sequence, and teaches how to test the variants for activity. Applicants believe this position is supported by the decision of the court in *In re Angstadt* (190 USPQ 214,1976 CCPA) which noted that inventors are not required to disclose a test using every species covered by the claims since such a requirement would force inventors to carry out a prohibitive number of actual experiments. The court in *Angstadt* found that if a disclosure were required to "provide guidance which will enable one skilled in the art to determine, *with reasonable certainty before carrying out an experiment*, whether the claimed product will be obtained, ...then all experimentation is undue since the term experimentation implies that the success of the particular activity is uncertain." Applicants believe the courts sentiments apply perfectly in the instant case. Contrary to the court opinion in *Angstadt*, the Examiner seems to be requiring Applicants to teach *with certainty*, which positional changes will result in the final protein having the stated activity. However, as noted above, such certainty is not required. Applicants have provided all of the necessary tools for the practitioner to make all of the claimed nucleic acid molecules, even if such making requires some experimentation. The Examiner seems to want to eliminate the need for any experimentation. However, the law is clear that some level of requirement to experiment is allowable; this sentiment is apparent in the holdings of the court in *In re Angstadt*. However, such sentiment was more clearly stated by the court in *In re Wands* (8 USPQ2d 1400,1988 CAFC) which stated" The test is not merely quantitative, since a considerable amount of experimentation is permissible if it is merely routine..." Applicants contend the screening of variant molecules for a specified activity, while perhaps being a fair amount of work, is routine and does not rise to the level of undue experimentation. Therefore, in view of the above, Applications submit the newly submitted claims are adequately enabled by the instant specification.

The Examiner has rejected Claims 11-16 under 35 U.S.C.§112, first paragraph, as failing to meet the enablement requirement. Applicants note claims 11-16 have been canceled. The

newly submitted claims do not refer to therapeutic uses of the instant nucleic acid molecules or to methods of regulating an immune response using the instant nucleic acid molecules.

CONCLUSION

Applicants believe the newly submitted claim set to be in condition for allowance and therefore solicit such from the Examiner. The Examiner is invited to contact the undersigned should any issues remain.

Respectfully submitted,

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